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| SCHIEF HARDIN, LLP PATENT DEPARTMENT 6600 SEARS TOWER CHICAGO, IL 60606-6473 | | | EXAMINER PANI, JOHN | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,980

Applicant(s)

BLOMBERG ET AL.

Examiner

JOHN PANI

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-53 and 80 is/are pending in the application.
- 4a) Of the above claim(s) 51 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-45, 47-50 and 80 is/are rejected.
- 7) ☒ Claim(s) 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/8/2009 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required. The claims refer to "signal attributes", but the specification does not include this terminology in a way which would allow one of ordinary skill in the art to recognize which features correspond to the claimed "signal attributes". It is suggested to carefully review and amend the specification to include the term "attributes" in connection with, for example "EKG-signal 26" and "EMG-signal 24" and "noise-signal 28".

Claim Objections

3. Claims 41, 43-45, 47, 48, and 53 are objected to because of the following informalities: In line 15 of claim 1, line 4 of claim 43, line 3 of claim 44, line 4 of claim 45, line 4 of claim 47, and line 2 of claim 48, it is suggested to insert --attribute-- after "EMG signal". In line 3 of claim 43, line 2 of claim 45, and line 3 of claim 53, it is suggested to insert --attribute-- after "EKG signal". In lines 2 and 4 of claim 47 it is suggested to insert --attribute--after "noise signal". Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 41-45 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,524,632 to Stein et al. ("Stein") in view of US Pat. No. 5,768,392 to Graupe ("Graupe").

In reference to Claim 41

Stein teaches a method for determining an EMG signal out of a raw signal comprising the steps of: obtaining a plurality of signals from a subject via a plurality of electrodes (160,162) configured to interact with the subject to detect signals from the diaphragm of the subject, each electrode having a signal channel associated therewith (col. 6 lines 30-45, each electrode is a channel); combining the respective signals of the

signal channels to form a multi-channel raw signal that contains an EKG contribution arising from an EKG signal of the subject and an EMG contribution arising from an EMG signal of the subject (col. 6 lines 35-40); and automatically removing EKG artifact from the EMG signal (col. 6 lines 49-68).

However, Stein does not appear to teach automatically electronically estimating an attribute of said contribution of said EKG signal of the subject to said raw signal and an attribute of said contribution of said EMG signal of the subject to said raw signal, to obtain an estimated EKG signal attribute and an estimated EMG signal attribute; and dependent on said estimated EKG signal attribute, automatically electronically determining an EMG window in a frequency range and frequency-domain filtering said raw signal only within said frequency range of said window to obtain said EMG signal as a filtered-out signal.

Graupe teaches a method (see col. 5 – col. 10) of determining an EMG signal out of a raw signal comprising obtaining a raw signal ($y(k)$) that contains an EMG contribution arising from an EMG signal of the subject and an unspecified noise contribution (see Fig. 16B); automatically electronically estimating (col. 5 line 45 - col. 6 line 3) an attribute of said contribution of said noise signal to said raw signal and an attribute of said contribution of said EMG signal of the subject to the raw signal, to obtain an estimated noise signal attribute ($N(f_i)$ or $P(n_i)$) and an estimated EMG signal attribute ($S(f_i)$); and dependent on said estimated noise signal attribute and said estimated EMG signal attribute, automatically electronically determining an EMG window in a frequency range and frequency-domain filtering said raw signal only within

said frequency range of said window to obtain said EMG signal as a filtered-out signal (see at least col. 6 lines 4-43 and col. 9 lines 28-45). Graupe teaches that this method allows for noise reduction without the need for a reference feed of the noise signal.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Stein by substituting the noise canceling method taught by Graupe (i.e. estimating attributes of the noise signal of interest –the ECG in this case-- and the information signal and using these to define a filter and thereby providing a clean signal of interest) for the ECG blanking of Stein, because the substitution would result in a clean EMG signal without totally removing sections of EMG contribution which results from the method of Stein.

In reference to Claim 42

Stein in view of Graupe teaches the method of claim 41 (see above) and Graupe further teaches filtering said EMG signal that is filtered out from said raw signal (col. 6 line 45 - col. 9).

In reference to Claim 43

Stein in view of Graupe teaches the method of claim 42 (see above) and Stein in view of Graupe further teaches automatically electronically dividing said window into at least two sub-windows with respectively different filtering criteria dependent on said estimated EKG signal and said estimated EMG signal (see Graupe col. 8 line 37- col. 8 line 14).

In reference to Claim 44

Stein in view of Graupe teaches the method of claim 41 (see above) and Stein in view of Graupe further teaches automatically electronically determining a width of said window dependent on said estimated EKG signal attribute and said estimated EMG signal attribute (see Graupe col. 6 lines 4-45, defining the filter determines its width).

In reference to Claim 45

Stein in view of Graupe teaches the method of claim 41 (see above) and Stein in view of Graupe further teaches the window has a lower frequency, and automatically electronically determining said lower frequency of said window dependent on said estimated EKG signal attribute and said estimated EMG signal attribute (see Graupe col. 6 lines 4-45, defining the filter determines its lower frequency).

In reference to Claim 47

Stein in view of Graupe teaches the method of claim 41 (see above) and Stein in view of Graupe further teaches automatically electronically estimating a noise signal attribute from said raw signal, and automatically electronically determining an upper frequency of said window dependent on said estimated EMG signal attribute and said estimated noise signal attribute (see Graupe col. 6 lines 4-45, defining the filter determines its lower frequency, the EKG signal is a noise signal).

In reference to Claim 80

Stein in view of Graupe teaches the method of claim 41 (see above) and Stein in view of Graupe teaches using said estimated EKG signal attribute and said estimated EMG signal attribute to identify a frequency range within said raw signal wherein said contribution of said EKG signal is weaker than said contribution of said EMG signal, and

determining said frequency range of said EMG window to substantially coincide with said frequency range in which said contribution of said EKG signal is weaker than said contribution of said EMG signal (By setting up a bandpass filter that allows the EMG signal through while not allowing the noise, i.e. EKG signal with Stein as modified by Graupe, this would at least be obvious because EKG has a lower contribution at higher frequencies than does EMG).

6. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein in view of Graupe as applied to claim 41 above and further in view of US Pat. No. 5,671,752 to Sinderby et al. ("Sinderby").

In reference to Claims 48-50

Stein in view of Graupe teaches the method of claim 41 but does not teach determining a middle frequency of the estimated EMG and using the middle frequency to monitor/measure at least muscle fatigue and muscle activity of the patient, activating a humanly perceptible alarm dependent on deviation of said monitored or measured muscle fatigue from a reference value, or automatically controlling a ventilator configured to interact with the patient to provide ventilation support to the patient dependent on said monitored or measured muscle fatigue. Sinderby teaches a method in which the center frequency of a diaphragmatic EMG signal is used to measure muscle activity fatigue and to optimize ventilator support (col. 10 lines 1-20). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Stein by using the central frequency of the diaphragmatic

EMG signal to measure muscle fatigue in order to automatically optimize ventilator support as taught by Sinderby because this substitution would predictably result in controlling a ventilator using a diaphragmatic EMG signal as taught by Sinderby. Additionally, by controlling the ventilator based on the diaphragmatic fatigue, a humanly perceptible signal would be produced in the form of the motion/sound of the ventilator in response to a deviation of the fatigue from a reference value.

Allowable Subject Matter

7. Claim 53 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 6/16/09

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736